NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOHN STREET,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. L.L.C., SANOFI-AVENTIS U.S., INC., SANOFI-SYNTHELABO, INC.,

Defendants.

Civil Action No. 3:07-cv-1182 (FLW)

GWENDOLYN NEWELL,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. L.L.C., SANOFI-AVENTIS U.S., INC., SANOFI-SYNTHELABO, INC.,

Defendants.

Civil Action No. 3:07-cv-1184 (FLW)

ROGER GOLDENBOGEN,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. L.L.C., SANOFI-AVENTIS U.S., INC., SANOFI-SYNTHELABO, INC.,

Defendants.

Civil Action No. 3:07-cv-1188 (FLW)

LORAINE BOOTH, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. L.L.C., SANOFI-AVENTIS U.S., INC., SANOFI-SYNTHELABO, INC., Defendants.	Civil Action No. 3:07-cv-1180 (FLW)
GEORGE DAWKINS, JR., Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. L.L.C., SANOFI-AVENTIS U.S., INC., SANOFI-SYNTHELABO, INC., Defendants.	Civil Action No. 3:07-cv-1186 (FLW) **OPINION**

This matter comes before the Court on motions to dismiss pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure brought by defendants, Bristol Myers-Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc., (collectively, "Defendants"). Plaintiffs John Street, Gwendolyn Newell, Roger Goldenbogen, Loraine Booth, and George Dawkins, Jr. (collectively, "Plaintiffs") bring separate suits against Defendants alleging that they suffered injuries as a result of Defendants' unlawful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of the

prescription drug Plavix®. In that respect, each of Plaintiffs' First Amended Complaints ("Amended Complaints") asserts various Ohio statutory and common law claims against Defendants. In the present matter, Defendants move to dismiss Count V, i.e., negligent misrepresentation claim, and Count VI, i.e., statutory fraud claim pursuant to Ohio's Consumer Sales Practice Act, Ohio Rev. Code §1345.01, et seq., asserted by each of the Plaintiffs. For the reasons that follow, Defendants' motions to dismiss are granted as to Counts V and VI.

I. Procedural History

On March 12, 2007, Plaintiffs, Ohio residents, filed Complaints against Defendants asserting claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.*, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*, the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, *et seq.*, New Jersey's Uniform Commercial Code, N.J.S.A. 12A:2-313, and the common law of the State of New Jersey, invoking this Court's diversity jurisdiction. (March 12, 2007 Complaints ¶¶ 7-9.) Plaintiffs are among a number of individual claimants[1] that lodged separate complaints[2] against Defendants in this district between October 2006 and March 2007, invoking this Court's diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing,

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[1] Initially, claims were filed on behalf of twenty-four individual claimants, however, a Michigan plaintiff in the matter of Felmlee v. Bristol-Myers Squibb Co., No. 06-6240, voluntarily dismissed her claim in February, 2008.

[2] A number of the twenty-three claimants were joined in their actions by spouses, asserting claims for loss of consortium.

labeling and/or the sale of Plavix. Id. A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in these matters.

In January 2007, prior to the filing of the instant actions, Defendants filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) in the matters of Hall v. Bristol-Myers Squibb, No. 06-CV-5203 (hereinafter, "Hall"), and Skilstaff v. Bristol-Myers Squibb, No. 06-CV-4965 (hereinafter, "Skilstaff"),[3] and indicated their intention to file similar motions in the other Plavix cases pending before this Court. In March 2007, this Court, without objection from the parties, administratively terminated Defendants' motions in Hall and Skilstaff having determined that two cases then pending before the New Jersey Supreme Court addressed the central issues to be decided by this Court on Defendants' motions to dismiss. The parties further agreed that all Plavix cases filed in this district be held in abeyance. Following the issuance of the New Jersey Supreme Court's decisions in Rowe v. Hoffman-LaRoche, 189 N.J. 615 (2007), and International Union of Operating Engineers, Local #68 v. Merck, 192 N.J. 372 (2007), the plaintiff in Skilstaff voluntarily dismissed the action and this Court granted Defendants' request to file a single omnibus motion to dismiss applicable to all personal injury Plavix lawsuits then pending in this district.

One of the main issues to be determined by this Court in the omnibus motion was the federal preemption of the plaintiffs' individual state law claims. In February 2008, however, in light of the fact that the Third Circuit had pending two separate cases,

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[3] The plaintiff in the matter of Skilstaff v. Bristol-Myers Squibb, is not among the twenty-three individual claimants seeking damages for personal injuries, rather Skilstaff was an Alabama third-party payor seeking certification of a class of third-party payors for violations of the New Jersey Consumer Fraud Act.

Colacicco v. Apotex, Inc., and McNellis ex. rel. DeAngelis v. Pfizer, Inc., on its docket regarding substantially similar preemption issues, as did the United States Supreme Court, Levine v. Wyeth, this Court administratively terminated the personal injury Plavix cases pending in this district and permitted plaintiffs to re-file amended complaints in the event there were viable claims after the decisions from the Higher Courts. Following the issuance of the Supreme Court's decision in Levine v. Wyeth, __ U.S. __, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of the plaintiffs filed an amended complaint. In the amended complaints, each individual plaintiff brought claims under the laws of the states in which they reside, rather than New Jersey, as originally plead. Thereafter, Defendants moved to dismiss certain counts of the amended complaint filed by each individual plaintiff. It is the Defendants' motions to dismiss Counts V and VI with regard to these Ohio Plaintiffs that this Court now considers.

II. Factual Background

The following version of events assumes Plaintiffs' allegations in their First Amended Complaints ("FAC") to be true because Defendants move pursuant to Fed.Civ.R.P. 12(b)(6). The Court will recount only those facts relevant to this Motion.

Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, the "Sanofi Defendants") partnered with Bristol-Myers Squibb Company ("BMS") to manufacture and market Plavix in the United States. FAC ¶¶ 2-5.[4] In April 1997, the Sanofi Defendants and BMS applied for a rare, priority regulatory review by the

[4] Because the Plaintiffs' First Amended Complaints are substantially identical, the Court will refer to them collectively, unless otherwise noted.

Food and Drug Administration ("FDA") clearing the way for Defendants to bring Plavix to market in November 1997. Id. at ¶ 12. According to Plaintiffs, Defendants heavily marketed Plavix directly to consumers through television, magazine, and Internet advertising, falsely touting Plavix "as a 'super-aspirin' that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin." Id. at ¶ 14. Plaintiffs allege that Defendants either knew or should have known, based upon their own studies, that not only was Plavix not more efficacious than aspirin in terms of preventing heart attacks and strokes, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder or death far outweighed any benefit from the drug. Id. at ¶ 15.

As evidence that Defendants were indeed aware of their false and misleading promotion of Plavix, Plaintiffs point to a November 1998 letter from the FDA wherein the FDA instructed Defendants to cease promoting Plavix for off-label use in patients undergoing coronary artery stent placement.[5] Id. at ¶ 19; Certification of Michele A. DiMartino, Esq. ("DiMartino Cert.") at ¶ 4, Ex. C. Plaintiffs also point to the same FDA reprimand wherein Defendants were instructed to cease promoting Plavix at an off-label dose, which was nearly four (4) times that of the recommended dosage. FAC at ¶ 19; DiMartino Cert. ¶ 4, Ex. C. In addition to criticizing Defendants for promoting Plavix for unapproved use, the FDA also criticized Defendants for overstating the safety profile of Plavix with respect to its use with other drugs. Id. at ¶ 20. In particular, Plaintiffs point to the fact that Defendants touted the safety of Plavix when combined with aspirin (known

[5] As discussed more fully infra, the Court will consider the extrinsic documents referenced in the FAC as they were explicitly relied upon by Plaintiffs in the FAC.

as "dual therapy") when, in fact, its safety had not been established. Id. According to Plaintiffs, Defendants' claim regarding the safety of dual therapy has now been proven to be untrue in a recent study published in the New England Journal of Medicine in April 2006 entitled Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (the "CHARISMA Study"[6]). FAC at ¶ 20; DiMartino Cert. at ¶ 3, Ex. B.

As further evidence of Defendants' allegedly false and misleading promotional practices, Plaintiffs point to a December 1998 letter from the FDA, wherein the FDA demanded that Defendants cease the distribution of advertising materials that claimed that Plavix has been proven more effective than aspirin. FAC at ¶ 21; DiMartino Cert. at ¶ 2, Ex. A. The FDA criticized Defendants' materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001, the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. FAC at ¶ 22; DiMartino Cert. at ¶ 5, Ex. D. Specifically, the FDA noted that the clinical evidence of the efficacy of Plavix is derived from Defendants' study entitled Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events Trial (the "CAPRIE Study"). Id. Defendants' promotional material depicted a 19.2% relative risk reduction for Plavix versus aspirin, yet the actual findings of the CAPRIE Study were that Plavix was not proven significantly more effective than aspirin. Id. Additionally, the FDA again instructed Defendants to cease claiming that the use of Plavix combined with aspirin was safe and effective. Id.

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[6] The CHARISMA Study derives its name from the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial, which was the subject of the article.

According to Plaintiffs, in addition to misinforming physicians and consumers through false and misleading promotional materials and advertising, Defendants' drug representatives also misinformed physicians regarding the proper types of patients who should be prescribed Plavix, the duration of its proper usage and the applications for which Plavix is safe and FDA approved. FAC at ¶ 23. Specifically, Plaintiffs point to the fact that the drug representatives have encouraged physicians to prescribe Plavix to a broad population who would receive the same therapeutic benefit from aspirin alone, without the purported risk of death, and to use Plavix for unapproved applications. Id. at ¶ 24.

Plaintiffs allege that after a nearly eight-year run of misleading physicians and the public regarding the safety and efficacy of Plavix, scientific studies now reveal that Plavix is in fact dangerous. Id. at ¶ 26. Citing a study published in The New England Journal of Medicine in January 2005 entitled Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding (the "Chan Study"), Plaintiffs note the dangers of Plavix. Specifically, Plaintiff contends that the Chan Study demonstrates the fallacy of Defendants' assertions that Plavix is safer and more effective for patients suffering from gastrointestinal intolerance to aspirin. Id. at ¶ 27. Plaintiffs point out that the Chan Study recommended that prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin, in light of the Study's findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Id. Plaintiffs additionally point to the Chan Study's finding that an aspirin a day plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec) is far more cost effective than paying for the four-dollar per day Plavix pill, which greatly increases the risk of stomach bleeding. Id.

at ¶ 28. Finally, citing the CHARISMA Study, Plaintiffs contend that Plavix plus aspirin ("dual therapy") is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events, and more significantly, does more harm than good in those patients without peripheral arterial disease or acute coronary syndrome in that it poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. Id. at ¶ 29.

Due to these alleged illegal practices, Plaintiffs assert, inter alia, statutory fraud claims pursuant to the Ohio Consumer Sales Practice Act, Ohio Rev. Code Ann. § 1345.01, et seq. ("OCSPA"), and Ohio state common law claims of negligent misrepresentation. These claims are the subject of the motions to dismiss. In connection with these two claims, Plaintiffs allege the following in Paragraph 31 of each of their individual Amended Complaints, which allegations constitute the only difference among each of the Amended Complaints:

> Plaintiff Gwendolyn Newell
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> 31. In 1998, Plaintiff was prescribed Plavix to treat multiple cardiovascular risks. In the Spring of 2005, Plaintiff developed frequent nausea, vomiting, and excessive fatigue. In June of 2005, she presented to the emergency department with these complaints. She was admitted to the hospital and was diagnosed with stomach ulcers and massive internal bleeding. She received a blood transfusion and underwent medical procedures to address her bleeding. The following day, she continued to experience dizziness and fainting and required an additional transfusion. After five days in the hospital she was discharged. She continues to have difficulty with stomach pain and nausea.
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> Plaintiff Roger Goldenbogen
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> 31. In 2002, Mr. Godenbogen was prescribed Plavix to treat multiple cariovascular risks. On or about January 29, 2004, Mr. Goldenbogen had a gastrointestinal hemorrhage that caused kidney failure. He required multiple transfusions and surgery to address his bleeding and additional treatment for kidney failure.

Plaintiff Loraine Booth

31. In November of 1999, Ms. Booth was prescribed Plavix plus aspirin (dual therapy) following placement of a cardiac stent. In January of 2003, Ms. Booth developed a severe gastrointestinal hemorrhage, which required a transfusion. Her massive blood loss caused permanent vision loss in her left eye.

Plaintiff George Dawkins, Jr.

31. In 2006, Mr. Dawkins was prescribed Plavix plus aspirin (dual therapy) to treat multiple cardiovascular risks. In July of 2006, Mr. Dawkins developed stomach pain which eventually necessitated hospitalization on or about August 31, 2006. Soon after his admission to the hospital, Mr. Dawkins became gravely ill and was taken to the intensive care unit where he remained in a coma for six days. Ultimately, Mr. Dawkins was hospitalized for seventeen days, during which time he required plasmapheresis to treat his TTP. Following his discharge, Mr. Dawkins suffered through a long convalescence and has permanent injuries due to the TTP caused by Plavix.

Plaintiff John Street

31. In January of 2005, Mr. Street was prescribed Plavix plus aspirin (dual therapy) following placement of a cardiac stent. In June of 2005, Mr. Street was at home and began throwing up large quantities of blood. He was rushed to the hospital where he underwent transfusions and a surgical procedure to address his massive gastrointestinal bleeding. He was placed on a ventilator in intensive case following the procedure. Eleven days later, he was discharged from the hospital.

As a result of the alleged injuries, Plaintiffs, in Count VI of their respective Amended Complaints, allege that Defendants violated the OCSPA by making "untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff, concerning the use and safety of Plavix." FAC at ¶ 101. In that connection, Plaintiffs allege that "Defendants knew or should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects." FAC at ¶ 99. Specifically, Plaintiffs allege that "Defendants' practice of promoting Plavix placed and

continues to place all consumers of Plavix at risk for serious injury and potentially lethal side effects." FAC at ¶ 103. Plaintiffs further allege that "Defendants' statements and omissions were made with the intent that the Plaintiff, and Plaintiff's prescribing physician, would rely on them." FAC at ¶ 104. As a result of the alleged illegal practices, Plaintiffs claim that they have "suffered severe and permanent physical injuries." FAC at ¶ 108.

Similarly, in Count V Plaintiffs allege that "Defendants falsely represented to Plaintiff in direct to consumer advertising and indirectly through misrepresentations to the prescribing physician, that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff's health." FAC at ¶ 82. Each Plaintiff claims that "[a]t the time the representations were made, Defendants concealed from Plaintiff and Plaintiff's prescribing physician information about the propensity of Plavix to cause great harm." FAC at ¶ 83. In that regard, Plaintiffs allege that "Defendants' misrepresentations were made by Defendants with the intent to induce Plaintiff to use Plavix, to Plaintiff's detriment." FAC at ¶ 85. Plaintiffs further allege that "Plaintiff and Plaintiff's healthcare provider justifiably relied on Defendants' misrepresentations and consequently, Plaintiff's ingestion of Plavix was to Plaintiff's detriment." FAC at ¶ 90.

Now Defendants move to dismiss Count V, the negligent misrepresentation claim, and Count VI, the OCSPA claim, of each of Plaintiffs' Amended Complaints. The Court will address the sufficiency of each of these claims in turn.

III. Standard of Review

When reviewing a motion to dismiss on the pleadings, courts "accept all factual

allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 561 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. As the Third Circuit has stated, "[t]he Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest 'the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of 'the necessary element'." Phillips, 515 F.3d at 234 (quoting Twombly, 550 U.S. at 556).

In affirming that Twombly standards apply to all motions to dismiss, the Supreme Court recently explained the principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949, 173 L.Ed. 2d 868 (2009); Fowler v. UPMC

Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).[7] "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 1950. Therefore, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." Id. Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Fowler, 578 F.3d at 211.

Before reaching the merits of Plaintiffs' claims, there is a threshold procedural question as to the documents and exhibits this Court may consider on this motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6). As previously referenced in this Court's discussion of the Factual Background, Plaintiffs supply this Court with several exhibits, including: (1) a December 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (2) a copy of the CHARISMA Study; (3) a November 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (4) a May 2001 FDA letter addressed to Sanofi-Synthelabo Inc.; and (5) the Chan Study. Additionally, the Defendants provide the Court with the November 17, 1997 approval letter for Plavix. Certification of Michael A. Tanenbaum, Esq., Ex. A. While generally a court may not consider matters outside the pleadings when ruling on a motion to dismiss, documents that are "integral to or explicitly relied upon in the complaint" may indeed be considered without converting a motion to dismiss into a motion for summary judgment. In re Rockefeller Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Accordingly, the referenced exhibits are properly before

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[7] The Court notes that because the briefing in this matter was filed only shortly after the United States Supreme Court's decision in Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009), counsel for Defendants moved for leave to file supplemental briefing addressing the standard of review applicable to the instant motion. This Court found additional briefing unnecessary and, accordingly, denied Defendants' request.

the Court on the instant motion to dismiss.

IV. The Ohio Consumer Services Practice Act Claim

In Count VI of Plaintiffs' FAC, Plaintiffs assert violations of Ohio's Consumer Sales Practice Act, Ohio Rev. Code Ann. §1345.01, et seq., ("OCSPA"). Defendants seek dismissal of Plaintiffs' OCSPA claims, arguing that the claims fail as a matter of law because they are exempt from liability pursuant to Ohio Rev.Code Ann. § 1345.12(A). Additionally, Defendants contend that Plaintiffs have failed to plead the requisite elements of the OCSPA claims and, further, that the claims lack the particularity required by Fed.R.Civ.P. 9(b).

The Court turns first to Defendants' contention that Plaintiffs' OCSPA claims fail as a matter of law because Defendants are exempt from liability pursuant to Ohio Rev.Code Ann. § 1345.12(A). The OCSPA specifically exempts a defendant from liability when the complained of conduct is "[a]n act or practice required or specifically permitted by or under federal law, or by or under other sections of the Revised Code . . . ." Ohio Rev.Code Ann. § 1345.12(A). Defendants argue that the alleged deceptive statements identified by Plaintiffs in the Amended Complaints fall under § 1345.12(A) and are exempted because FDA authorization of those statements is undisputed in this case. Defendants reason that Plavix was approved by the FDA in November 1997 and, therefore, any advertisements in relation to its marketing would also have been authorized by the FDA. Because Plaintiffs concede in the Amended Complaints that Plavix was reviewed by the FDA so that it could be brought to market in 1997, Defendants contend that this Court must necessarily find that the statutory exemption applies. Def. Br. at 3. Citing Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 246 (3d Cir. Del. 2007), vacated on other

grounds, 129 S.Ct. 1578 (2009), Defendants assert that Congress has expressly given the FDA authority over prescription drug advertising in the Federal Food, Drug & Cosmetic Act. Defendants reason that the FDA, in turn, authorizes pharmaceutical companies to market and sell their products. Def. Rep. Br. at 2-3 (citing 21 U.S.C. § 355; 21 U.S.C. § 352(n)). Citing the exemption provision as support, Defendants contend that OCSPA is only intended to regulate those areas in which consumers are unprotected.

In Bergmoser v. Smart Document Solutions, LLC, 268 Fed.Appx. 392, 395 (6th Cir. 2008), the Sixth Circuit considered whether § 1345.12(A) operated to bar OCSPA claims brought by consumers who claimed the defendant medical records company's practice of charging more than the actual cost it paid for mailing the medical records to consumers constituted a violation of OCSPA. Plaintiffs in Bergmoser argued that the defendant was bound by a schedule of charges set forth in Ohio's Medical Records Statute, Ohio Rev.Code Ann. § 3701.741, which specifically proscribed the practice of charging more than the actual cost of postage incurred by a medical records company. Id. The Bergmoser court concluded that the plaintiffs' claims were excluded under § 1345.12(A), finding that because another provision of Ohio's Medical Record Statute expressly authorized medical records companies to enter into contracts to provide services and placed no limitations on the terms of the agreements, the defendant's conduct was indeed specifically permitted under the Medical Record Statute and therefore exempt from suit under the OCSPA. Id.

Plaintiffs counter that simply because Plavix was approved by the FDA and underwent regulatory review does not mandate application of § 1345.12(A). Plaintiffs argue that while the FDA may have approved Plavix, it did not authorize Defendants to engage in unfair, deceptive and/or unconscionable consumer sales practices. In support of

their position, Plaintiffs cite Pomianowski v. Merel Norman Cosmetics, Inc., 507 F.Supp. 435 (S.D. Oh. 1980) a case in which an Ohio district court considered whether § 1345.12(C), which exempts claims for personal injury and death from the provisions of OSCPA, required that a plaintiff's claims for violations of the OCSPA be dismissed. The Pomianowski court concluded that the statute did not preclude a cause of action under OCSPA merely because personal injury results from the claimed deception, but, rather, only precludes statutory recovery for such personal injury in the event that the same should be found to have been caused by the deception. Pomianowski, 507 F.Supp. at 438.

The Court finds Plaintiffs' reliance on Pominanowski unpersuasive. The inquiry, however, does not end there, as there is no support or authority for Defendants' bald assertion that "any action or transaction involving Plavix® would be authorized or administered by the Food and Drug Administration." Def. Br. at 3. The fact that the FDA regulates the labeling and marketing of pharmaceuticals is not a *fait accompli* to the application of the exemption. While the FDA may indeed regulate the promotion and marketing of Plavix, the parties have failed to provide the Court with any factual information or legal analysis involving the regulatory scheme at issue. The issue for this Court's determination is whether the promotional materials that Plaintiffs identify as deceptive were nevertheless in compliance with FDA regulations governing those materials. If indeed Defendants were compliant, then the Court could find the statutory exemption applicable. If, however, Defendants' promotional materials were not authorized by the FDA's regulatory scheme in that they were either not in compliance or are not among the type of materials that the FDA monitors then the statutory exemption would be inapplicable. However, in the absence of adequate briefing from the parties as to these

issues the Court is not in a position at this juncture to make a ruling on the issue. Accordingly, this Court finds that Plaintiffs' claims under the OCSPA should not be dismissed based upon § 1345.12(A).

The Court now turns to Defendants' contention that Plaintiffs' Amended Complaints must be dismissed because they fail to plead the requisite elements of the OCSPA claim and, further, that the claim lacks the particularity required by Fed.R.Civ.P. 9(b). The OCSPA "prohibits a seller from committing 'an unfair or deceptive act or practice in connection with a consumer transaction.'" Mercy Health Partners of Southwest Ohio v. Miller, No. A0301165, 2005 WL 2592674, at * 3 (Oh.Ct.Com.Pl. Sep. 30, 2005) (quoting Ohio Rev.Code Ann. § 1345.02). Pursuant to § 1345.02 of the OCSPA, "[n]o supplier shall commit an unfair or deceptive act or practice in connection with a consumer transaction. Such an unfair or deceptive act or practice by a supplier violates this section whether it occurs before, during, or after the transaction." The provisions of §1345.03 provide, in relevant part, "[n]o supplier shall commit an unconscionable act or practice in connection with a consumer transaction. Such an unconscionable act or practice by a supplier violates this section whether it occurs before, during, or after the transaction."

A violation of § 1345.02 does not require that the deception be knowing or intentional, whereas § 1345.03 does require "that the supplier has taken advantage of the consumer." Millington v. Financing Solutions, No. 3-07-37, 2008 WL 2581728, *10 (Ohio App.Ct. Jun. 30, 2008). It is unclear from Plaintiffs' Amended Complaints whether they assert their claims under § 1345.02 or § 1345.03 as they are not labeled therein and may arguably fall under either statutory provision or both as plead. Plaintiffs reference the claims as falling under § 1345.02 in their briefs in opposition to the instant motions,

whereas Defendants reference § 1345.03 in discussing the elements of Plaintiffs' statutory claims. Regardless of which provision the claims fall under, it is clear that the claims are distinct from common law fraud claims. Considering both statutory provisions, one district court noted that "[u]nlike a fraud claim, where a plaintiff must allege harm above and beyond the misrepresentation and reliance thereon, a cause of action accrues under the Consumer Sales Practices Act as soon as the allegedly unfair or deceptive transaction occurs." Delahunt v. Cytodyne Technologies, 241 F.Supp.2d 827, 835 (S.D.Ohio 2003).

At the outset, the Court notes that while the parties dispute the applicability of Rule 9(b) to Plaintiffs' OCSPA claims, the Court need not address the issue as Plaintiffs' OCSPA claims do not even satisfy the more lenient standards of Rule 8(a). Last year, addressing the clarifications as to a litigant's pleading requirement stated by the United States Supreme Court in Twombly, 550 U.S. 544, the Court of Appeals for the Third Circuit provided the district courts with guidance as to what pleadings are sufficient to pass muster under Rule 8. See Phillips v. County of Allegheny, 515 F.3d at 230-34. Specifically, the Third Circuit, quoting Twombly, observed as follows:

> "[W]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's [Rule 8] obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." . . . "[T]he threshold requirement of Rule 8(a)(2) [is] that the 'plain statement' possess enough heft to 'sho[w] that the pleader is entitled to relief.'" . . . "Factual allegations must be enough to raise a right to relief above the speculative level."

Phillips 515 F.3d at 231-32 (quoting Twombly 550 U.S. at 555). As previously noted, this pleading standard was further refined by the United States Supreme Court in Ashcroft v. Iqbal, 129 S. Ct. 1949 wherein the Supreme Court held that in all civil actions:

> [T]he pleading standard Rule 8 announces . . . demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. . . . The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"
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> . . . .
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> Two working principles underlie [the] decision in Twombly. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . . . Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not "show[n]" - "that the pleader is entitled to relief." Fed. Rule Civ. Proc. 8(a)(2).
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> . . . .
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> Rule 8 does not empower [a claimant] to plead the bare elements of his cause of action, affix the label "general allegation," and expect his complaint to survive a motion to dismiss.

Iqbal, 129 S.Ct. at 1949-54 (quoting Twombly 550 U.S. at 555-57). Since Iqbal, the Third Circuit has required the district courts to conduct, with regard to Rule 8 allegations, a two-part analysis when presented with a motion to dismiss:

> First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. [See Iqbal, 129 S.Ct. at 1949-50]. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief" [in light of the definition of "plausibility" provided in Iqbal.] In other words, a complaint must do *more than allege the*

> *plaintiff's entitlement to relief.* A complaint has to "show" such an entitlement with its facts. See Phillips, 515 F.3d at 234-35. As the Supreme Court instructed in Iqbal, "[w]here the well-pleaded facts do not permit the court to infer more than the *mere possibility of misconduct, the complaint has alleged-but it has not 'show [n]'-'that the pleader is entitled to relief.'"* Iqbal, 129 S.Ct. at 1949-50. This "plausibility" determination will be "a context-specific task that *requires the reviewing court to draw on its judicial experience and common sense."* Id.

Fowler, 578 F.3d at 210-11 (emphasis supplied).

This Court finds that Plaintiffs have failed to plead anything other than bald conclusory allegations in support of their respective OCSPA claims. The only factual allegations in the FAC which are not boilerplate and which provide details with regard to each particular Plaintiff are those in Paragraph 31, wherein Plaintiffs describe generally that they were prescribed Plavix and sustained injury after ingesting the drug. With regard to their own experiences, or that of Plaintiffs' prescribing physicians, in connection with Defendants' purported false and misleading promotional materials and practices, Plaintiffs' Amended Complaints are silent. Even if this Court were to find that Plaintiffs have plead facts sufficient to support the allegations that Defendants engaged in deceptive or unconscionable practices under OCSPA, it is clear that the FAC does not set forth sufficient facts to support any nexus between the alleged unlawful acts and Plaintiffs' injuries. The FAC sets forth the following allegations in the numbered paragraphs in each FAC filed on behalf of Plaintiffs:

> 105. The Plaintiff purchased and used Plavix for personal, family or household purposes and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices.
>
> 107. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff has suffered ascertainable loss-economic loss that includes the purchases of Plavix and additional

> out-of-pocket healthcare related costs, for which the Defendants are liable to the Plaintiff for treble [sic] Plaintiff's actual damages.
>
> 108. As a direct and proximate cause of the Defendants' acts of consumer fraud, the Plaintiff further suffered severe and permanent physical injuries.

The conclusory nature of Plaintiffs' allegations mandates dismissal. Although the Court's research has not revealed any cases in which Ohio courts have directly addressed the issue of whether reliance is an element of a claim under § 1345.02, there are a number of unreported cases, including two from the Sixth Circuit, that have addressed the connection that must be shown between the unlawful acts and the injury. Noting the lack of Ohio case law directly addressing the issue, one district court noted with respect to the issue of reliance:

> two unreported cases from the Sixth Circuit Court of Appeals have taken divergent paths to reach a similar result. In Temple v. Fleetwood Ent., Inc., 133 Fed.Appx. 254 (6th Cir. 2005), the Court held that in order to make out a prima facie claim under the OCSPA, the plaintiff must "show a material misrepresentation, deceptive act or omission that impacted his decision to purchase the item at issue." Id. at 266. Conversely, in Butler v. Sterling, Inc., No. 98-3223, 2000 WL 353502 (6th Cir. Mar. 31, 2000), the Court stated that "a showing of subjective reliance is probably not necessary to prove a violation of the OCSPA." Id. at *4. Nevertheless, the Court held the plaintiff must establish that his or her damages were proximately caused by the defendant's conduct. Id. In other words, in order for a plaintiff to prevail under the OCSPA, there must be a nexus between the defendant's conduct and the alleged injury. Id. In Butler, however, the Court affirmed the district court's grant of summary judgment in favor of the defendant on the grounds that plaintiff could not reasonably have relied on the alleged fraudulent omissions and because the omissions were not the proximate cause of her damages. Id. at *5. Harmonizing these two cases, whether it be termed an issue of reliance or an issue of proximate cause, an appropriate rule is that where the defendant is alleged to have made material misrepresentations or misstatements there must be a cause and effect relationship between the defendant's acts and the plaintiff's injuries.

Lilly v. Hewlett-Packard Co., No. 1:05-CV-465, 2006 WL 1064063, *5 (S.D.Oh. Apr. 21, 2006). This interpretation of the requisite elements of a claim under OCSPA comports with the decision by the Ohio Court of Common Pleas in Mercy Health Partners of Southwest Ohio v. Miller, 2005 WL 2592674, at * 3, wherein the court dismissed a counterclaim brought under § 1345.02 not only because it was devoid of factual allegations of deception but also because it failed to assert that the claimant was given any of the alleged misleading statements or was told anything that was untrue. Here, Plaintiffs have failed to plead any facts which could support a nexus between the purported deceptive practices and Plaintffs' injuries. While Plaintiffs make exhaustive allegations regarding Defendants' alleged illegal practices by relying on FDA correspondence and scientific studies, the FAC fails to allege any facts linking Defendants' conduct with Plaintiffs' resultant injuries. Plaintiffs fail to identify any specific advertisements that were viewed by themselves or their prescribing physicians. In fact, Plaintiffs fail to even identify their prescribing physicians. Moreover, the necessary factual allegations to support Plaintiffs' claims are not the sort that are within the control of, and therefore subject to concealment by Defendants.[8] Accordingly, Plaintiffs have failed to state a claim upon which relief can

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[8] Indeed, in that connection, Plaintiffs are uniquely equipped to determine from their prescribing physicians, whether the physician received such promotional literature or information from Defendants' sales representatives. Even where factual information may be within the domain or control of Defendants, Plaintiffs must still "accompany [his] legal theory with factual allegations that make [his] theoretically viable claim plausible." In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to "avoid dismissal," a complaint must also delineate at least the nature and the scope of a plaintiff's efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiff has failed to comply with these requirements. Plaintiffs' FAC makes no allegations that the information required for Plaintiffs to meet their Rule 9(b) obligation is

be granted.

V. Negligent Misrepresentation Claim

"Under Ohio law, a person is liable for negligent misrepresentation when: (1) he supplies false information (2) for the guidance of others in their business transactions, (3) causing pecuniary loss to plaintiff, (4) who justifiably relies upon the information, (5) if he fails to exercise reasonable care or competence in obtaining or communicating the information." In re National Century Financial Enterprises, Inc., 504 F.Supp.2d 287, 321 (S.D. Ohio 2007). 552) (citing Delman v. Cleveland Heights, 41 Ohio St.3d 1, 4, 534 N.E.2d 835, 838 (Ohio 1989). Defendants argue that Plaintiffs' claims of negligent misrepresentation fail as a matter of law because they are not in the business of supplying information and, therefore, Plaintiffs are unable to satisfy a requisite element of the tort. Defendants assert that they are in the business of manufacturing pharmaceutical drugs, not information, and their actions fall outside the scope of a negligent misrepresentation claim. Citing Hamilton v. Sysco Food Services of Cleveland, Inc., 170 Ohio App.3d 203, 208 (Ct.App. 2006) and Nichols v. Ryder Truck Rentals, Inc., No. 65376, 1994 WL 285000, at *4 (Ct.App. Jun. 23, 2994), Defendants argue that where a defendant is not in the business of supplying information, the defendant may not be held liable for negligent misrepresentation.

The case law supports Defendants' position. "[T]he elements for negligent misrepresentation 'require (1) a defendant who is in the business of supplying information; and (2) a plaintiff who sought guidance with respect to his business transactions from the defendant." Hamilton v. Sysco food Services of Cleveland, Inc., 866 N.E.2d 559, 563 (Ohio

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solely within Defendants' control.

Ct.App. 2006) (quoting Nichols v. Ryder Truck Rentals, Inc., 1994 WL 285000, at *4). In Nichols, the Ohio Court of Appeals specifically rejected application of the tort of negligent misrepresentation in the employer/employee context noting:

> persons who are in the business of supplying information for the guidance of others typically include attorneys, surveyors, abstractors of title and banks dealing with non-depositors' checks. The business transactions of the alleged injured party are usually those involving lease or insurance agreements. No court in Ohio, however, has held the tort of negligent misrepresentation applicable to the employer-employee relationship.

Id. (*Citations omitted*). There is some dispute among the district courts in Ohio as to whether a "special relationship" is required to establish a negligent misrepresentation claim. In In re National Century Financial Enterprises, Inc., Investment Litigation, 580 F.Supp.2d 630, 646-47 (S.D.Ohio 2008), the court observed:

> Several cases from the federal district court for the Northern District of Ohio have imposed a 'special relationship' requirement for a negligent misrepresentation claim. See Doe v. Sex-Search.com, 502 F.Supp.2d 719, 731 (N.D.Ohio 2007); Ziegler v. Findlay Indus., 464 F.Supp.2d 733, 738 (N.D.Ohio 2006); Hayes v. Computer Assoc. Intern. Inc., No. 03:02CV7452, 2003 WL 21478930 (N.D.Ohio Jun. 24, 2003). These cases have stated that "[a] core requirement in a claim for negligent misrepresentation is a special relationship under which the defendant supplied information to the plaintiff for the latter's guidance in its business transaction." Doe, 502 F.Supp.2d at 731; Ziegler, 464 F.Supp.2d at 738. "Usually the defendant is a professional (e.g. accountant who is in the business of rendering opinions to others for their use in guiding their business, and the plaintiff is a member of a limited class." Doe, 502 F.Supp.2d at 731; Ziegler, 464 F.Supp.2d at 738.
>
> A case from the Southern District of Ohio observed that the Ohio Supreme Court's definition of a negligent misrepresentation claim does not include a special relationship as "a formal element." National Mulch and Seed, Inc. v. Rexius Forest By-Products Inc., No. 2:02-cv-1288, 2007WL 894833, at *9 (S.D.Ohio Mar. 22, 2007). The court found that a "special relationship" is best viewed as "a characterization of the requirements that for liability to exist: (1) the defendant must provide false information for the guidance of the plaintiff in its business

> transactions and (2) the plaintiff must be the person or one of a limited group of person for whose benefit and guidance the defendant intends to supply the information or knows that the recipient intends to supply it." 2007 WL 894833, at *11.

Based on the foregoing, the National Century Financial Enterprises court concluded that "even though a 'special relationship' is not an express element of a negligent misrepresentation claim, it is an apt characterization of the requirements that the defendant supply false information in a business transaction for plaintiff's guidance and that the plaintiff be the person or part of a limited class for whom defendant intended to supply the information." Id. at 647. The court went on to note that "Ohio Courts have accordingly drawn a line whereby misrepresentations to the public-at-large are not actionable but misrepresentations to a person or limited category of people whom the speaker or supplier intends to benefit or guide are actionable." Id. The court in National Century Financial Enterprises held that where note offerings were targeted to a select class of institutional investors, not to the investing public, the plaintiff had sufficiently alleged that it was part of a limited class whose reliance on certain rating conditions was foreseeable. Id. at 648.

Even if Plaintiffs could establish that they, by virtue of their prescribing physicians, were part of a limited class to whom Defendants intended to supply the information, a fact which they have not plead, the Court nevertheless finds that Plaintiffs have failed to satisfy the element. The information at issue was not supplied for use by Plaintiffs or their prescribing physicians in business transactions, as those have been interpreted by the courts in Ohio. Accordingly, the Court finds that Defendants are not subject to a negligent misrepresentation cause of action under Ohio law. Plaintiffs' negligent misrepresentation claims are dismissed.

VI. Conclusion

For the foregoing reasons, Defendants' motions to dismiss Counts V and Count VI of Plaintiffs' Amended Complaints are granted. Plaintiffs' claims under OCSPA are dismissed without prejudice. Plaintiffs shall have leave to file a motion to amend their respective Amended Complaints if they seek to assert the claim, but must cure the deficiencies as outlined by the Court herein. The motions to dismiss Count V as to each of the Plaintiffs is granted and their respective claims are dismissed with prejudice.

Dated: December 30, 2009

/s/ Freda L. Wolfson
United States District Judge